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The Honorable Mehmet Oz, M.D.
Centers for Medicare and Medicaid Services
Office of the Administrator
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Delivered via electronic mail for file code CMS-5546-P

RE: Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model

Dear Administrator Oz:

The ADAP Advocacy Association appreciates the opportunity to submit comments on the proposed Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") Model (file code CMS-5546-P). We commend the Administration and the Centers for Medicare & Medicaid Services ("CMS") for exploring innovative approaches to address prescription drug costs in Medicare Part D. We believe the proposal shows promise. However, we write to urge CMS to modify the model to ensure that patients *directly* benefit from any savings generated. We believe that addressing this issue is essential, and we cannot support the proposal unless a modification is made to address this shortcoming.

About ADAP Advocacy
ADAP Advocacy's mission is to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for patients living with HIV/AIDS. ADAP Advocacy works with advocates, community members, health care providers, government officials, patients, pharmaceutical companies, and other stakeholders to raise awareness, offer patient education programs, and foster greater community collaboration.

ADAP Advocacy is the only national grassroots organization focused on ADAPs authorized under the Ryan White HIV/AIDS Program and on ensuring adequate resources nationwide to eliminate or prevent waiting lists for services. Our purpose is to better engage patients living with HIV/AIDS by providing a platform whereby they can offer their personal experiences, challenges, knowledge, insight, and solutions to solving this perpetual problem.

It has long expressed its serious concerns about the out-of-pocket costs borne by patients living with HIV/AIDS and the need to ensure that efforts to reduce drug therapy costs benefit patients directly with those out-of-pocket costs.

Background

The GUARD Model is one of two pricing initiatives proposed by the Administration, alongside the Global Benchmark for Efficient Drug Pricing (GLOBE) Model, which applies to Medicare Part B. Under GUARD, CMS proposes to assess inflation rebate amounts for certain Part D medications using a benchmark derived from international pricing information, rather than current domestic benchmarks.

We note that the model relies on a rebate framework—requiring manufacturers to return a portion of the purchase price when drug prices exceed benchmark thresholds. While rebate models can reduce overall system spending, they often fail to reduce patients' out-of-pocket costs at the pharmacy counter because the rebated price is not available at the point of sale, when patients' out-of-pocket costs are determined and collected.

Thus, patient cost-sharing is typically calculated based on a drug's higher list price, with patients receiving no benefit from the rebate. As a result, patients continue to pay deductibles and coinsurance obligations based on inflated prices—even when rebates later lower net costs to plans or the federal government. In effect, the healthcare system benefits from rebate savings in these circumstances, while patients do not.

Out-of-Pocket Costs Directly Affect Health Outcomes

ADAP Advocacy exists for one reason: to ensure that patients living with HIV/AIDS can access and remain on life-saving medications without cost standing in the way.

Decades of research and lived experience confirm that out-of-pocket costs directly affect medication adherence. When patients face higher costs, they skip doses, delay refills, or abandon prescriptions altogether. Public health data demonstrates that cost-related non-adherence remains a disturbing and persistent barrier for patients living with HIV/AIDS.

These behaviors have real consequences. Reduced adherence leads to lower rates of viral suppression, poorer individual health outcomes, and increased costs for Medicare and the healthcare system.

Importantly, research shows that even modest increases in cost-sharing can have outsized effects. Prescription abandonment rates rise sharply when out-of-pocket costs increase from $0 to even $10. Persistence in therapy declines as costs rise. For HIV treatment, where uninterrupted adherence is essential, even small financial barriers can undermine public health progress.

Put simply: when patients pay more, adherence suffers—and when adherence suffers, health suffers, and costs rise--dramatically.

Accordingly, GUARD holds tremendous promise, but from a patient perspective, that promise can only be realized if patients share in the savings generated by the program.

GUARD Must Guarantee *Patient* Savings

While the GUARD proposal promises hope that lower benchmark pricing may indirectly benefit patients, it does not *require* that rebate savings be passed through at the point of sale.

The proposal states that manufacturers might reduce their net prices in response to GUARD rebate obligations. Some manufacturers have lowered list prices under other federal pricing reforms, while others have not. In connection with the first ten Medicare Fair Price drugs, for example, six of those products have reduced their Wholesale Acquisition Cost list prices, but, importantly, four have not. The possibility that patients might benefit from GUARD is not enough; the policy must *ensure* that patient benefit is an inherent and core element of GUARD as it is finalized.

CMS should finalize and implement the GUARD Model only with a clear, enforceable mechanism that ensures patients share directly in the savings generated. This can be accomplished in multiple ways. It can be accomplished, for instance, by:

- Requiring that patient cost-sharing under GUARD be calculated based on an estimated post-rebate price, rather than the list price;
- Mandating a defined percentage reduction in patient deductible, copayments, or coinsurance in anticipation of GUARD rebate amounts;
- Structuring the model so that rebates are reflected in real time at the pharmacy counter; or
- Requiring patients themselves receive a rebate, post-dispense, reflective of a modified out-of-pocket cost using the GUARD net price in the calculation, instead of the list price.

Since under that last option, patients would need to pay a higher initial sum, that alternative is the least attractive option. The danger is that such an initial, higher cost may well dissuade patients from adhering to their drug therapy.

GUARD holds meaningful promise as a tool to reduce Medicare drug spending. However, without a guarantee that patients will benefit directly at the pharmacy counter, the model risks repeating a central flaw of many existing rebate systems—system-wide savings that fail to translate into affordability for patients that can drive adherence.

ADAP Advocacy respectfully urges CMS to condition implementation of the GUARD Model on explicit, enforceable requirements that rebate savings be shared with beneficiaries at the point of sale.

Thank you for taking the time to consider our request. For additional information, please do not hesitate to contact me by email at brandon@macsata.org or phone at (305) 519-4256. Thank you.

Sincerely,

Brandon M. Macsata
CEO

cc: William Sarraille, Esq., Select Counsel
Marcus J. Hopkins, Health Policy Lead Consultant